

**AMENDMENT TO COMMITTEE PRINT**  
**OFFERED BY MR. MARKEY OF MASSACHUSETTS**  
**AND MR. ROGERS OF MICHIGAN,**  
**(PED-DEVICES\_001, June 11, 2007)**

Page 17, line 9, strike “to clearance of a premarket notification under section 510(k),” and insert “to clearance of a premarket notification under section 510(k), for a pediatric population or pediatric subpopulation,”.

Page 17, line 13, strike “that is” and insert “or that is indicated for pediatric populations or subpopulations or is”.

Page 18, after line 11, insert the following (and make such technical and conforming changes as may be necessary):

1       “(c) DISPUTE RESOLUTION.—A manufacturer may  
2 request review under section 562 of any order or condition  
3 requiring postmarket surveillance under this section. Dur-  
4 ing the pendency of such review, the device subject to such  
5 a postmarket surveillance order or condition shall not be  
6 deemed misbranded under section 502(t) or otherwise in  
7 violation of such order or condition or a related require-

1 ment of this Act unless deemed necessary to protect the  
2 public health.”.

Beginning on page 18, strike line 12 and all that follows through the end of the bill (and make such technical and conforming changes as may be necessary).